



Agence canadienne
d'inspection des aliments

Canadian Food
Inspection Agency

Canada Organic Office
Confidential

**PEER REVIEW REPORT
OF
THE UNITED STATES NATIONAL ORGANIC
PROGRAM**

Date: November 29 - December 3, 2010

Prepared by: Michel R. Saumur, Valeriya Staykova and Ken Bruce

Approved by: CFIA Management and the US-Canada Organic Equivalence Arrangement
- Steering Committee

SECTION 1 - EVALUATION TEAM AND AGENDA

Date of Commencement: 29 November 2010

Date of Completion: 3 December 2010

Canadian Review Team:

Michel Saumur (CFIA COO)	- Team Leader
Valeriya Staykova (CFIA COO)	- Team Member
Ken Bruce (CFIA COO)	- Team Member

ACKNOWLEDGEMENT

Canada's review team thanks National Organic Program officials for the efforts extended in coordinating this peer review.

SECTION 2 - Introduction and Background

2.1 Pre-Peer Review Activities

On June 17, 2009, the Government of Canada entered into an arrangement on the trade of organic products with the United States. This arrangement was the result of considerable review by both the United States and Canada. Both countries entered into an arrangement recognizing our national organic systems as equivalent but the arrangement is subject to the following conditions:

Imports from the United States into Canada

1. Agricultural products produced with the use of sodium nitrate shall not be sold or marketed as organic in Canada.
2. Agricultural products produced by hydroponic and aeroponic production methods shall not be

sold or marketed as organic in Canada.

3. Agricultural products derived from animals must be produced according to livestock stocking rates as set out in CAN/CGSB-32.310-2006.

Exports to the United States from Canada

1. Agricultural products derived from animals treated with antibiotics shall not be marketed as organic in the United States.

Since the USDA and the Canadian Food Inspection Agency (CFIA) signed the US-Canada Organic Equivalency Arrangement, the National Organic Program (NOP) and the Canada Organic Office (COO) have worked to ensure a smooth implementation.

Under the Arrangement, the parties agreed to establish a high-level policy Steering Committee consisting of representatives from the Office of the United States Trade Representative, the USDA Foreign Agricultural Service, the Department of Foreign Affairs and International Trade (DFAIT), Agriculture and Agrifood Canada (AAFC), and the CFIA. Its purpose is to oversee implementation of the Arrangement and to guide the activities of the COO and the NOP.

As a result of the ongoing Working Group and Steering Committee meetings, the NOP notified certifying agents in November 2010 that for agricultural products certified under the US-Canadian Equivalency Arrangement, the statement "Certified in compliance with the terms of the US-Canada Organic Equivalency Arrangement" must accompany products that are produced under the terms of the arrangement. It must appear on documentation travelling with products shipped to Canada; it may also be included on the organic certificate, a transaction certificate, a statement on a bill of lading, purchase order, or any other affirmative attestation.

NOP also clarified that sodium nitrate is not allowed in raw or processed agricultural products and must be phased out completely for organic ingredients used in processed products shipped under the arrangement.

2.2 Comparison of information/documentation: Results

During the establishment of the organic arrangement it was also agreed to conduct peer reviews of each respective organic program/regime in 2010. The countries agreed to utilize the following references in developing the review procedures:

ISO 17040 - Conformity assessment general requirements for peer assessment of conformity assessment bodies and accreditation bodies, and

ISO/IEC Guide 68:2002 - Arrangements for the recognition and acceptance of conformity assessment results.

2.3 Peer Review

Canada conducted a peer review of the United States NOP between November 29 and December 3, 2010. This report covers the results from Canada's assessment activities.

2.3.1 Objectives of the Peer Review

Canada's objective in conducting the review was to observe how the United States NOP implemented the US-Canada Organic Equivalency Arrangement.

By conducting the peer review, Canada expected to gain a better understanding of the structure and functions of the NOP program and to assess the rigour of controls associated with the overall program, specifically with regard to the controls associated with the (3) three critical variances on the US side. In addition, the review offered COO an opportunity to observe the overall effectiveness of the operations with regard to achieving the objectives of the organic program in the United States. Finally, through the review, COO has been able to glean information needed to inform the US-Canada Organic Equivalency Arrangement Technical Working Group and Steering Committee of future work needed between the two countries.

2.3.2 Peer Review Procedure

The peer review was performed in accordance with COO Peer Review Procedure and consisted of the following elements:

- opening meeting
- on-site verification
- closing meeting
- report

This procedure requires that we plan and perform the assessment to obtain sufficient, appropriate evidence to provide a reasonable basis for our observations and conclusions based on our assessment objectives.

Prior to initiating the peer review process, the appointed Canadian peer review team was provided with a verbal proposal for the peer review process including: the proposed number of people conducting the review, their names and affiliation; expected duration; the proposed peer review plan which included visits to accredited certification agencies and certified operators.

The activities subject to the peer review process included: document review, record assessment, personnel interviews, visits to NOP's main office, visits to NOP accredited certification agency facilities, visits to processing operations and farming/producers of organic products.

Appendix 2 of US-Canada Organic Equivalency Arrangement Letter provides the authority for this peer review:

“Following advance notice from the CFIA, the USDA shall permit the CFIA to conduct on-site evaluations to verify that the USDA's certifying agents are carrying out the requirements of the United State's organic certification program, including through visits to agent facilities and to production facilities and farms that agents have certified. The USDA shall cooperate and assist the CFIA, to the extent permitted under domestic law, in carrying out such evaluations.”

SECTION 3 - PEER REVIEW OBSERVATIONS

The observations presented in this report cover all components of the United States NOP structure and all components listed below were assessed:

The peer review included onsite visits to the:

November 29, 2010 - USDA NOP - Main Office - Washington D.C.

November 30 and December 1, 2010 - USDA Audit Review and Compliance - Main Office - Fredericksburg, Virginia

November 30, 2010 - NOP Accredited Certifying Agent -Main Office, San Deigo CA

December 1, 2010 - 2 certified operators - City of Industry, CA and Irwindale, CA

December 2, 2010 - NOP Accredited Certifying Agent - Main Office, Santa Cruz, CA

December 2, 2010 - Certified operator, Santa Cruz, CA

December 3, 2010 - Certified operator and interview with another Certified Operator, Santa Cruz, CA

During the visit to the NOP main office, the NOP provided the Canadian peer review team with regulatory text that had been updated August 24, 2010 and a Program Handbook: Guidance and Instructions for Accredited Certifying Agents & Certified Operations dated October 20, 2010.

Prior to the visits to the organic operator premises, the Canadian peer review team requested that each NOP Accredited Certification Agency (ACA) provide the operator's organic systems plan and the operator's file.

The Canadian peer review team was accompanied by two NOP officials throughout each step of

the review. At each of the certified operators visited, the team was accompanied by at least one representative of the respective ACA. Any issues of concern or perceived non-compliance were immediately brought to the attention of the accompanying official or representative.

3.1 US NOP Competent Authority -November 29, 2010

The peer review started with an opening meeting at the NOP main office in Washington.

3.1.1 Organization/Structure

The Competent Authority - NOP is divided into five levels. The USDA office of the Secretary heads up the hierarchy, followed by mission areas and agencies. It is at the next level, the program level, that the NOP is located.

Within Agriculture Marketing Service (AMS) there are 10 Programs, including the NOP. NOP have (3) three divisions: Standards, Accreditation & International Activities, and Compliance & Enforcement. Assessment activities required under the NOP accreditation process are led by Accreditation and International Activities Division (AIA) with the assistance of the Livestock and Seed Program's audit, review and Compliance (ARC) Branch. Appeals are handled by the Compliance and Analysis Program compliance, Safety and Security Division.

There are (31) people employed by the NOP. The NOP has recently increased in number. It is understood that this growth has been rapid. Even though this is a mature program and the staff are very knowledgeable, more communication with regards to consistent implementation of the US Canada organic equivalence arrangement is needed.

Another structure within NOP is the National Organic Standards Board (NOSB), a 15-member board appointed by the Secretary of Agriculture under the Federal Advisory Committee Act. NOSB influences the decisions on organic farming in the NOP and meets twice a year. Recently the board petitioned the NOP to prohibit the use of hydroponic and aeroponic processes under the NOP.

Observation #1

The NOP has requested the NOSB to consider removing the annotation that would prohibit the use of sodium (Chilean) nitrate in order to facilitate trade for US organic agricultural products.

3.1.2 Documentation

It was noted that the documentation system regarding roles and responsibilities of the NOP staff is reasonably complete.

Both the NOP and the ARC are programs under the Agricultural Marketing Service. ARC provides auditing services by agreement for the NOP. The NOP maintains decision-making authority.

On an annual basis, the NOP receives information about the operations from each ACA and publishes general information about such operators on their website.

In addition, the certification bodies are required to submit annual reports to the NOP. In the past it was the ARC that was responsible to review these reports and it hasn't conducted a review since 2008. During the discussion with NOP representatives it was noted that since 2009 the requirements for the annual report from ACA have been modified and the annual reports are simply compiled without any review. When a copy on an annual report was requested by the Canadian peer review team it was explained that the NOP program specialist would be able to provide it to the team when the Canadian peer review team visited the ARC Branch office. During the interview with program specialists, the Canadian peer review team was told that recently the files have been reassigned to the Regional Accreditation Managers and the filing system has been changed.

As in Canada, the US was unable to illustrate, by means of statistical data, the size of the US sector and specifically the amount of products shipped to Canada under the US-Canada Organic Equivalency Arrangement.

Nevertheless, it was encouraging to see that the Foreign Agricultural service is leading a project to track the import and export of organic products.

As a result of USDA and the Organic Trade Association's data collection, 24 import codes and 22 export codes were suggested for the most widely traded organic products. The final set was available for use beginning in January 2011 when the International Trade Commission published them in the US Tariff Schedule.

The review team noted that NOP was unable to illustrate, by means of statistical data, the size, volume, and number of shipments of organic products leaving the US destined for Canada or organic products certified to the terms of the US Canada Equivalence arrangement.

The NOP Compliance and Enforcement Division presented the NOP complaint process which has been recently revamped. NOP took over the complaints in 2008. Prior to 2008, complaints

were handled by US AMS Compliance and Analysis Programs. NOP Compliance and Enforcement Division has established an intake process; database; assigning of a case number and preliminary review process as well as complete investigatory process. All the complaints are registered in a complaint log.

While retail surveillance is a part of the Canada Organic Regime, it is not part of the NOP formal review which is system based. Some of the USDA accredited certifying agents have comprehensive retail surveillance programs. It was noted that the NOP Compliance and Enforcement Division investigation process is the primary retail surveillance system, which captures complaints as well as retail stores and trade shows.

3.1.3 Controls

The National Organic Program is responsible for the accreditation of the Certifying Agents (CAs).

Those are private, foreign, or State entities accredited to certify farms or processing facilities to the USDA organic standards. NOP accredited CAs are located throughout the United States and around the world and are responsible for determining that certified operations are in compliance with the Act (OFPA) and the Regulations (NOP Standards).

During the negotiations of the US-Canada Organic Equivalency Arrangement it was noted that NOP did not require NOP ACAs to meet ISO Guide 65. However, it was understood that a large percentage of the ACA's did meet the requirements of ISO Guide 65. Currently 50 CA's are accredited by NOP for organic certification within the US. Although both CAs visited during the review meet the ISO Guide 65 requirements and are audited by ARC, it is noted that more of the NOP Accredited Certification Agencies (around 2/3) are not ISO Guide 65 compliant.

It was reported to the Canadian peer review team that Certifying Agents not participating in the ISO Guide 65 accreditation program were on the list of certification agencies that were eligible to certify products going to Canada.

NOP Comments:

During the negotiations of the US-Canada Organic Equivalence Arrangement it was noted that NOP did not require NOP ACAs to be accredited separately under ISO Guide 65 . However it was understood that some ACAs did meet the requirements of ISO Guide 65 and were accredited to Guide 65 as needed for accreditation in other countries.

3.1.4 Communication

NOP indicated that communication had been further enhanced this past year between the NOP and the ACAs. The linkages have been established and considerable effort has been made to open up the lines of communication which is often a two-way dialogue.

NOP continues to improve communication tools such as its website, disseminating guidance in a standardized method by publishing program handbooks, draft guidance, policy memos and questions and answers.

3.2 NOP Accreditation Activities

3.2.1 Organization/Structure

NOP is the competent authority responsible for accrediting certification bodies.

It was explained that recently there have been changes made to the NOP accreditation process. The Canadian peer review team was made aware of those changes during the opening meeting at the NOP main office.

During the negotiation process, it was Canada's understanding that all the accrediting activities were conducted by the ARC and only the final accreditation decision was made by the NOP. On October 4, 2010 a work agreement was signed between the NOP and the ARC Branch which specifies the new roles and the responsibilities of the two groups. The NOP Accreditation & International Activities Division assumed responsibility for conducting the Corrective Action Review as part of the (re)accreditation review and assessment cycle. Prior to the change, the ARC conducted corrective action reviews.

Currently, the NOP accreditation and re-accreditation process includes a number of activities that are assigned to NOP employees or ARC Branch employees. The NOP accreditation cycle is five years and the Canadian peer review team was told that according to the cycle the ACAs will be the subject of on-site visits every two and half years.

During the NOP Accreditation and International Activities Division (AIA) presentation it was mentioned that NOP will conduct proactive compliance assessments.

The NOP Program Handbook from October 20, 2010 does not discuss these types of audits. Canada would respectively ask the NOP to provide further clarification on these types of audits.

NOP Comments:

The NOP handbook is not an all inclusive book and many operating procedures are maintained as part of the NOP quality management system. In addition to assessments and audits required by the accreditation process, the NOP conducts proactive compliance audits and reviews to

focus on certain programmatic or geographic areas. Reviews are conducted at the discretion of the NOP management team and on an as- needed basis.

3.2.2 Documentation

The primary focus during the visit to the ARC office was to assess ARC's ability to become a Conformity Verification Body under the Canada Organic Regime which is different from the activities that ARC performs under the NOP program.

The Canadian peer review team visited the ARC Branch office and reviewed ARC records to assess compliance to all areas contained within the scope of the assessment. Personnel records, meeting records, internal audit report, complaints log, and clients' files were reviewed. ARC Accreditation Manager had no difficulty providing relevant documents upon request. Most of the documentation related to the NOP accrediting activities is maintained by NOP employees, not the ARC Branch.

During the interview with the NOP program specialist, located at the ARC office, the Canada peer review team was told that recently ACA's files have been reassigned to the Regional Accrediting Managers (RAMs) and the filing system has been in a process of re-design. Although it was challenging for the RAMs as well as for the NOP program specialist to retrieve the requested documentation during the audit, copies of those were provided to the Canada peer review team at a later date.

3.2.3 Controls

The ARC Branch provides verification services to suppliers of agricultural products (including services). These services are offered through the Quality System Verification Programs (QSVP). There are a variety of programs within QSVP including the USDA ISO Guide 65 Program. The ARC Branch also conducts accreditation services for the NOP program in accordance with the work agreement between ARC and NOP.

ARC Branch has a quality management system as well as an accreditation system based on ISO/IEC 17011:2004. The ARC Branch has a sufficient number of well trained and experienced auditors that conduct ISO Guide 65 compliance audits.

ARC applies the ISO/IEC Guide 65 as well as the relevant guidance when assessing the Certification bodies accredited by the ARC Branch and NOP requirements when ARC is working with NOP.

3.2.4 Communication

The ARC Accreditation manager confirmed that she participates in meetings organised by the NOP accrediting division.

3.3 NOP Accredited Certification Agency

Two members of the Peer Review team visited two NOP ACAs and met officials from both certification agencies. The team interviewed the two agencies personnel to determine their ability to provide organic certification services and to assess their knowledge of organic certification and the terms of the US-Canada Organic Equivalency Arrangement. The team also reviewed documents/files of the operators that the team planned to visit. Both of these ACAs were accredited to NOP and they also met ISO Guide 65 requirements under ARC Branch accreditation.

It was clarified by the NOP that while NOP incorporated all relevant ISO Guide 65 requirements when developing its regulations, some documentation requirements were deemed redundant or unnecessary in consideration of other U.S. Federal requirements. While many NOP accredited certifiers have opted to gain ISO Guide 65 accreditation to participate in other countries certification schemes, compliance with ISO Guide 65 is not a requirement under the NOP.

3.3.1 Organization/Structure

Both ACAs were well established and have international clients. Organizational structure was well understood by all ACA staff interviewed. There did not appear to be any concerns with these structures.

3.3.2 Documentation

It was observed that documents were well organized, profiles of operations, inspector files, inspection reports, inspector reviews for consistency in certification, certified products, cycle, date of inspection, time to complete inspection, issuing of inspection reports, and complaints are dealt with adequately and that complaint files are well maintained.

3.3.3 Controls

One ACA highlighted that the US organic producers who have used sodium (chilean) nitrate on

an annual basis in their operations can still sell their products as certified to the NOP in the US. However, they indicated that NOP-compliant fresh products may be resold to Canadian produce brokers. These fresh products could enter Canada without the proper certification/attestation statement. In addition to this comment, another ACA indicated that partial equivalency arrangements or exceptions to these trade arrangements can be more troublesome for the ACAs than certifying to the country requirements.

3.3.4 Communication

It was observed that both ACAs maintain efficient communication with certified operators through newsletters, e-mails, and websites. Communication between the two ACAs and inspectors is adequate and all the necessary information is provided to the inspectors in a timely manner.

Communication between NOP and the two ACAs is satisfactory and is not limited to the surveillance activities performed by the NOP. NOP provides a program handbook, draft guidance and policy memos. It was also mentioned by several of the ACA's staff that the NOP website is an excellent communication tool for all NOP stakeholders.

The review team also noted that one ACA raised the point that they greatly appreciated the clarity that the NOP Policy Memorandum – Dated November 4, 2010 – has provided.

The attestation statement for agricultural products certified under the US-Canada Organic Equivalency Arrangement has been very helpful, however, the ACA indicated that the NOP Questions and Answers document that describes the US-Canada Determination of Equivalence - Question 1 states: “ If their products are to be exported to Canada and meet the NOP labelling requirements, they may be labelled accordingly and shipped to Canada.” This statement confuses US organic operators shipping to Canada.

NOP Comments:

Although it is generally understood that exported products must meet the labelling requirements of the receiving country, NOP has revised Question 1 to make this explicit.

3.4 Organic Operators

3.4.1 Organization/Structure

As part of its on-site assessment, the Canadian review team visited two processors and two

organic production operations.

Neither of the operations visited shipped organic products directly to Canada. During the evaluation the team interviewed the operations personnel to determine the operator's ability to certify organic products to the US-Canada Organic Equivalence Arrangement. It was noticed that all the operators were well versed in organic agriculture and the US National Organic Program. The only exceptions are listed in the following areas.

3.4.2 Documentation

All operators demonstrated excellent record keeping. All operators visited during the review had current copies of the organic systems plan for the Canadian team to review. The only exception was one operator who was not able to produce the requested documents.

3.4.3 Controls

Two operators indicated that they had not received unannounced visits.

NOP Comments:

Unannounced visits are not a regulatory requirement under the NOP certification.

3.4.4 Communication

It was noticed that the communication between the operator and certification body is well established, open and often a two-way dialogue. The operator can contact the NOP ACAs anytime, and response is received in a timely manner. When the operator wants to file a complaint about an ACA he knows who to contact.

SECTION 4 – COMMENTS - CONCLUSIONS

GENERAL COMMENTS

4.1 - The US exports a considerable volume of organic products to Canada. It is estimated that Canada is the largest estimated export market for US organic products. Nearly 70 percent of Canada's organic consumption comes from imports, and 90 percent of those imports come from the United States. Organic produce and processed foods are estimated to make up the majority of US organic products exported to Canada.



COMMENTS FOR FURTHER DISCUSSION:

4.2 Canada respectfully requests results of NOP request to NOSB to prohibit the use of Chilean Nitrate in Organic products. This decision will assist the USCOEA WG to clarify the US policy on the issue and to determine it's potential as a critical variance within the USCOEA.

4.3 NOP has modified its accreditation process. Currently, the NOP accreditation and re-accreditation processes include a number of activities that are assigned to the NOP employees or ARC Branch employees which differs from the accreditation process which was discussed during the US-Canada Organic Equivalency Arrangement discussions.

NOP Comments:

The NOP and ARC have indeed made some minor changes in the responsibilities for performing certain audit functions and the interface between ARC and the NOP . NOP will be glad to provide updated working instructions reflecting these changes.

5.0 - Next Steps

The NOP and the CFIA Peer Review Reports will be available at the same time.